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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,476	02/21/2001	Ching Ming Chung	3669-0103P	6205

2292 7590 07/03/2002

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EXAMINER
YU, MISOOK

ART UNIT	PAPER NUMBER
1642	11

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/788,476	Applicant(s) CHUNG ET AL.	
	Examin r Misook Yu	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *3-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Seq. alignment

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1 and 2 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that all of the pending inventions are "inter-twined", such that examinations of all pending claims would not be unduly burdensome. This is not found persuasive because each invention groups I-XII are distinct for the reasons for reasons of record and have acquired a separate status in the art as shown by their different classification. The search required for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, examination of all of pending inventions would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claims 1-14 are pending, and claims 1 and 2 are examined on merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1and 2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the expression" in line 2. There is insufficient antecedent basis for this limitation in the claim. Fixed

Claim 1 recites "a related cancer" but it is not clear what the metes and bounds are for a related cancer.

Claim 2 recites the limitation "the nucleotide sequence" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 recites "low stringency conditions" but it is not clear what the metes and bounds are for low stringency conditions are. The specification at page 24 lines 10-27 vaguely describes conditions that might or might not meet the "low stringency conditions" but does not define what low stringency conditions are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of full scope of the claimed invention. Claim 1 is drawn to any DNA molecule that is differentially expressed in human hepatocellular carcinoma (HCC) or related cancer. The specification provides evidence for only two DNA molecules, i.e. SEQ ID NO:1 and 3 which encode hcc-1 protein, and are expressed in HCC patients shown Figure 4. Based on these two DNA molecules, one cannot predict the types of additional DNA molecules which will result in differential expression in human hepatocellular carcinoma (HCC) or related cancer. Since the additional DNA molecules include a large number of unpredictable DNA molecules, possession of only two DNA molecules is not seen as sufficient to reasonably convey possession of the entire DNA molecues that are differentially expressed in human hepatocellular carcinoma (HCC) or related cancer. It is concluded that applicants adequately describes SEQ ID NO:1 and 3.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of full scope of the claimed invention. Claim 2 is drawn to a genus of DNA molecules with various structural similarities to SEQ ID NO:1 or 3. The specification provides evidence for only two DNA molecules, i.e. SEQ ID NO:1 and 3 which encode hcc-1 protein, and are expressed in HCC patients shown Figure 4. Based on these two DNA molecules, one cannot predict the types of additional DNA molecules which will result in differential expression in human hepatocellular carcinoma (HCC) or related cancer. Since the additional DNA molecules include a large number of unpredictable DNA molecules, possession of only two DNA molecules is not seen as sufficient to reasonably convey possession of the entire genus that is differentially expressed in human hepatocellular carcinoma (HCC) or related cancer. It is concluded that applicants adequately describes SEQ ID NO:1 and 3.

Claims 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1 and 3, does not reasonably provide enablement for any and all DNAs that are at least 60% similar to SEQ ID NO:1 or 3, or capable of hybridizing to SEQ ID NO:1 or 3 under low stringent conditons. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 2 is broadly drawn to DNA variants, defined in terms of the degree of difference in structure from SEQ ID NO:1 or 3. The specification teaches that SEQ ID NO:1 and 3 can be used to as diagnostic marker for human HCC in Figure 4. The specification does not teach any method of use for DNA molecules that are not expressed in human HCC. The specification does not teach if the DNA variants other than SEQ ID 1 or 3 can be differentially expressed in human HCC. Considering the broad scope of the claims, and the limited teachings of the specification, it is concluded that undue experimentation would be required to enable the full scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US PAT. 5,866,329 (02 Feb. 1999).

Claim 1 is drawn to any DNA molecule that is differentially expressed in human hepatocellular carcinoma (HCC) or related cancer. US PAT. 5,866,329 teaches a DNA molecule, SEQ ID NO:1 that is differentially expressed in human hepatocellular carcinoma (HCC). See abstract, column 2 line 41-55, Examples 4-9 in columns 9-11, SEQ ID NO:1 in column 13 and 14, and claims 25-41. drop

Thus, US PAT. 5,866,329 anticipates instant claim 1.

Claims 1and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO9845436-A2 (15 Oct. 1998).

Claims 1 and 2 are drawn to any nucleotide sequence that is at least about 60% similarity to SEQ ID NO:1 or 3, or capable of hybridizing to SEQ ID NO:1 or 3 under low stringency conditions. Claim 1 and 2 recite the claimed nucleic acid as differentially expressed in HCC or related cancer. However, this limitation is viewed as a recitation of intended use and therefore is not given weight in comparing the claim with the prior art. Claims 1 and 2 read on the ingredient *per se*, which is sequence of nucleotides that is at least about 60% similarity to SEQ ID NO:1 or 3, or capable of hybridizing to SEQ ID NO:1 or 3 under low stringency conditions.

WO9845436-A2 teaches a nucleotide sequence that is at least about 60% similarity to SEQ ID NO:1 or 3, or capable of hybridizing to SEQ ID NO:1 or 3 under low stringency conditions. See page 199 and claim 1. Also note the sequence alignment.

Thus, WO9845436-A2 anticipates claims 1 and 2.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu, Ph.D.
June 25, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

office, relevant page see attached seq. alignment

GAATTCGGCC TTCATGGCCT AGCAGGTCAG GAGCCCGGGG AAGGCCCAGA GGTACTCCAA 60
AGGGGGCCGG CTGGTATCTG AAGGCCCCTT GCAGTTAGTG TGTTGTTGAG CTGTGGGCAT 120
GAACATGCCA CAGGCAGACA CTGTTTAGCC AGGGTTTTAA GAAACACGGA GGGTCCTGTG 180
GATCTGGAGT TCATTTGTCA GGACAGGGAT GGGGACCCCT CTGAAGTATT CACTGTGGGC 240
TGAGGGGTGC TGGCCACACA ACCTCTGTGG GAGGCATCTC TTGCAGTGAA GCTGTTGGTC 300
CTCAGTTCAG TGCCCACTGA GGGTAACCAG GCCCCAGCTC TGCACCCCCA CTCGAG 356

(2) INFORMATION FOR SEQ ID NO:337:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 392 base pairs
(B) TYPE: nucleic acid
(C) STRANDEDNESS: double
(D) TOPOLOGY: linear

(ii) MOLECULE TYPE: cDNA

(xi) SEQUENCE DESCRIPTION: SEQ ID NO:337:

GAATTCTAGA CCTGCCGCAG CACAATCCCG TGGACAGAGC TTACTCCATC TAACTCGTTT 60
TCAAGTGCAT GATTTTCACT TTCACTTTTC CTTTTTCCTT ATTATGTTGC TTAACTTGTA 120
CAGTGGCAAC TGAAATGCAT TTCAGAAATA GGAGGTTTCG TCCAGCACCC TCTGCAGCCT 180
TGGTGCCTGT AGCTCTGGAC TTCCCTGGGC CTTTCCCTGT GGGAGGGCCC TGTAGACCAC 240
ATCAGGGTGG GGTGGGGGTC ACTTGGCAAA AAGGGCCGAG GTCTGGTGAT GTGGTTCCCA 300
GGATCTGGAA CCTCTCCCAC CCCTCCTGCA GTTGGACTGA ATTCTTCCCT TTCATCCGAA 360
GAAACCCACT TGCTGTTTCC AGCCAACTCG AG 392

(2) INFORMATION FOR SEQ ID NO:338:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 266 base pairs
(B) TYPE: nucleic acid
(C) STRANDEDNESS: double
(D) TOPOLOGY: linear

(ii) MOLECULE TYPE: cDNA

(xi) SEQUENCE DESCRIPTION: SEQ ID NO:338:

GCAAGATGGC GACCGAGACG GTGGAGCTCC ATAAGCTAAA GCTTGCCGAA CTAAAGCAAG 60
AATGTCTTGC TCGTGGTTTG GAGACCAAGG GAATAAAGCA AGATCTTATC CACAGACTCC 120
AGGCATATCT TGAAGAACAT GCTGAAGAGG AGGCAAATGA AGAAGATGTA CTGGGAGATG 180
AAACAGAGGA AGAAGAAACA AAGCCCATTG AGCTCCCTGT CAAAGAGGAA GAACCCCCTG 240
AAAAAACTGT TGATGTGGCT CTCGAG 266

(2) INFORMATION FOR SEQ ID NO:339:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 288 base pairs
(B) TYPE: nucleic acid
(C) STRANDEDNESS: double
(D) TOPOLOGY: linear

(ii) MOLECULE TYPE: cDNA

(xi) SEQUENCE DESCRIPTION: SEQ ID NO:339:

GAATTCGGCC TTCATGGCCT AAACAATGAA TAAAGCCAAG CCAGTTCCTG CCCCCGTGGA 60

PA (HUMA-) HUMAN GENOME SCI INC.
XX
PI Rosen CA, Barash SC, Ruben SM;
XX
DR WPI; 2001-483426/52.
XX
PT Nucleic acids encoding human immune/hematopoietic antigen polypeptides,
PT useful for preventing, diagnosing and/or treating cancers and
PT metastasis -
XX
PS Disclosure; SEQ ID NO 38930; 3071pp + Sequence Listing; English.
XX
CC AAK54951 to AAK64702 encode the human immune/haematopoietic antigen (I)
CC amino acid sequences given in AAM82170 to AAM91921. (I) have cytostatic
CC activity, and can be used in gene therapy and vaccine production. (I)
CC proteins and polynucleotides may be used in the prevention, diagnosis and
CC treatment of diseases associated with inappropriate (I) expression. For
CC example, they may be used to treat disorders associated with decreased
CC expression by rectifying mutations or deletions in a patient's genome
CC that affect the activity of (I) by expressing inactive proteins or to
CC supplement the patients own production of (I). Additionally, (I)
CC polynucleotides may be used to produce the secreted (I), by inserting
CC the nucleic acids into a host cell and culturing the cell to express the
CC protein. (I) proteins and polynucleotides may be used to prevent,
CC diagnose and treat immune/haematopoietic-related diseases, especially
CC cancers and cancer metastases of haematopoietic-derived cells. AAK64703
CC to AAK87694 represent human immune/haematopoietic antigen genomic
CC sequences from the present invention. AAK54942 to AAK54950 and AAM82169
CC represent sequences used in the exemplification of the present invention.
XX
SQ Sequence 9453 BP; 2869 A; 2071 C; 2294 G; 2219 T; 0 other;

Query Match 31.5%; Score 281.4; DB 22; Length 9453;
Best Local Similarity 99.6%; Pred. No. 4.5e-65;
Matches 282; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

```
Qy     612 agaggcaaagaagaggaaaagagcagagcgctttgggattgcctgatgaaaagttcctga 671
           | ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    8949 ACAGGCAAAGAAGAGGAAAAGAGCAGAGCGCTTTGGGATTGCCTGATGAAAAGTTCCTGA 8890

Qy     672 tactttctgttctccagtgttttccatttctctccttcttcttggtcacatatatgcctа 731
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    8889 TACTTTCTGTTCTCCAGTGTTTTCCATTTCTCTCCTTCTTCTTGGTCACATATATGCCTA 8830

Qy     732 aatgcacagtcatgtgcctacgtcctgcctcgcaatgagggagcatgtaccccaggtaca 791
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    8829 AATGCACAGTCATGTGCCTACGTCCTGCCTCGCAATGAGGGAGCATGTACCCCAGGTACA 8770

Qy     792 tccatgaactgcggcagcagtttgacttattgctgtttcagctttaaggttgttgtgttt 851
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    8769 TCCATGAACTGCGGCAGCAGTTTGACTTATTGCTGTTTCAGCTTTAAGGTTGTTGTGTTT 8710

Qy     852 ttgtttttgattatgttgcttgttaataaaaaaaaaatagaaaa 894
           |||||||||||||||||||||||||||||||||||||||||||||
Db    8709 TTGTTTTTGATTATGTTGCTTGTTAATAAAAAAAAATAGAAAA 8667
```

RESULT 14
AAV89379
ID AAV89379 standard; cDNA; 266 BP.
XX
AC AAV89379;
XX
DT 15-FEB-1999 (first entry)
XX
DE EST clone CL152.
XX
KW Human; secreted protein; expressed sequence tag; EST; haematopoiesis;
KW tissue growth; activin; inhibin; chemotaxis; chemokinesis; haemostatic;
KW receptor; ligand; thrombolytic; anti-inflammatory; cadherin; anti-tumour;
KW gene therapy; ss.
XX
OS Homo sapiens.
XX
PN WO9845436-A2. (618 pp)
XX
PD 15-OCT-1998.
XX
PF 10-APR-1998; 98WO-US06955.
XX
PR 10-APR-1997; 97US-0838821.
XX
PA (GEMY) GENETICS INST INC.
XX
PI Agostino MJ, Jacobs K, Lavallie ER, McCoy JM, Merberg D;
PI Racie LA, Spaulding V, Treacy M;
XX
DR WPI; 1999-070077/06.
XX
PT New polynucleotides encoding human secreted proteins - derived from
PT e.g. human blood, kidney, foetal lung, placenta, testes, brain,
PT ovary, pituitary, retina and colon cDNA libraries.
XX
PS Claim 1; Page 199; 618pp; English.
XX
CC The present sequence represents a human expressed sequence tag (EST).
CC The polynucleotide, which is a secreted EST, and the encoded protein
CC are predicted to have useful biological activities which would make
CC them suitable for treating, preventing or ameliorating medical
CC conditions in humans and animals, although no supporting data is
CC given. Suggested activities include nutritional activity, immune
CC stimulating or suppressing activity, haematopoiesis regulating
CC activity, tissue growth activity, activin/inhibin activity,
CC chemotactic/chemokinetic activity, haemostatic and thrombolytic
CC activity, receptor/ligand activity, anti-inflammatory activity,
CC cadherin/tumour invasion suppressor activity, tumour inhibition
CC activity. The polynucleotide may also be useful for gene therapy.
XX
SQ Sequence 266 BP; 94 A; 52 C; 73 G; 47 T; 0 other;

Query Match 28.9%; Score 258.6; DB 20; Length 266;
Best Local Similarity 98.5%; Pred. No. 1.3e-59;
Matches 261; Conservative 0; Mismatches 4; Indels 0; Gaps 0;

```
Qy      21 caagatggcgaccgagacggtggagctccataagctaaagcttgccgaactaaagcaaga 80
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2 caagatggcgaccgagacggtggagctccataagctaaagcttgccgaactaaagcaaga 61

Qy      81 atgtcttgctcgtggtttggagaccaagggaataaagcaagatcttatccacagactcca 140
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      62 atgtcttgctcgtggtttggagaccaagggaataaagcaagatcttatccacagactcca 121

Qy     141 ggcatatcttgaagaacatgctgaagaggaggcaaatgaagaagatgtactgggagatga 200
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     122 ggcatatcttgaagaacatgctgaagaggaggcaaatgaagaagatgtactgggagatga 181

Qy     201 aacagaggaagaagaaacaaagcccattgagctccctgtcaaagaggaagaaccccctga 260
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     182 aacagaggaagaagaaacaaagcccattgagctccctgtcaaagaggaagaaccccctga 241

Qy     261 aaaaactgttgatgtggcagcagag 285
           |||||||||||||||||   |||
Db     242 aaaaactgttgatgtggctctcgag 266
```

RESULT 15
AAX85623
ID AAX85623 standard; cDNA; 591 BP.
XX
AC AAX85623;
XX
DT 06-SEP-1999 (first entry)
XX
DE Novel cDNA sequence from a mouse blastocyst cDNA library.